

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte DONALD E. GILLESPIE

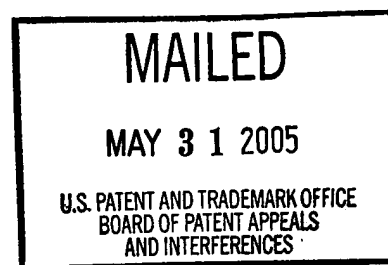
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Appeal No. 2005-0929  
Application No. 09/852,519

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ON BRIEF

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Before ELLIS, ADAMS and GRIMES, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the examiner's final rejection of claims 1-8, all the claims remaining in the application. Claims 9-21 have been canceled.

Claims 1, 5 and 8 are representative of the subject matter on appeal and read as follows:

1. A punctum plug which is more easily visualized when positioned within a punctual canal, the plug comprising:

a body having an outwardly exposed surface when so positioned; and

a substance causing at least the outwardly exposed surface to contrast with surrounding tissue, such that the use of the substance causes the plug to be more easily visualized than if the substance were not present.

5. The punctum plug of claim 1, wherein the plug is illuminated with light at an illumination wavelength, and wherein the substance generates radiated light at a wavelength other than the illumination wavelength.

8. The punctum plug of claim 5, wherein the radiated light is outside the visible spectrum and further including a detector for detecting the radiated light.

The examiner relies on the following references:

|                                   |           |               |
|-----------------------------------|-----------|---------------|
| L'Esperance, Jr.<br>(L'Esperance) | 5,300,020 | Apr. 5, 1994  |
| Seder et al.<br>(Seder)           | 4,959,048 | Sep. 25, 1990 |
| Freeman                           | 3,949,750 | Apr. 13, 1976 |
| Gwon et al<br>(Gwon)              | 5,178,635 | Jan. 12, 1993 |

The claims stand rejected as follows:

I. Claims 1-4 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by L'Esperance.

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II. Claims 1-8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Seder or Freeman in view of Gwon.

We reverse both rejections.

### Background

As set forth in the specification, it is well known in the art that tears are responsible for lubricating the human eye and guarding it against contaminants.

Specification, p. 1, para. 2. The specification discloses (page 1, lines 5-15) that

. . . tears are secreted by the lachrymal gland, and the excess fluid is carried away by the lachrymal or punctal [sic, punctual] canals into the lachrymal sac, and along the nasal duct into the cavity of the nose.

A condition called “dry eye” may occur when inadequate tears are produced. Generally, this is the result of improper body chemistry, injury, or the aging process. This condition may affect either or both of the eyes and causes the eyes to feel scratchy and irritated. Artificial eye drops may provide temporary relief from the problem, but a long term solution is desirable.

One long-term solution involves the reversible closing of one of the drain ducts of the affect [sic, affected?] eye. This is done by inserting a plug into one of the ducts, or punctual canals.

As indicated by claims above, the present invention is directed to a punctum plug which is visible when positioned in a recipient.

Discussion

I. Anticipation

In view of its brevity, we reproduce the examiner's arguments in their entirety.

The examiner argues (Answer, pages 3-4) that

L'Esperance discloses an implantable device for controlling drainage flow of aqueous fluid from the anterior chamber of the eye. (abstract). Accordingly, such device of L'Esperance meets the limitations of the instant punctum plug. The device of L'Esperance contains an outwardly exposed surface (see figure 1, element # 17; col. 2, lines 55-65). L'Esperance further teaches that his plug contains an energy-absorbing compound such as fluorescein, Indocyanine green, methylene blue or Rose Bengal at the tubular section of the plug. Accordingly, L'Esperance anticipates the limitations of the instant claims [1-4 and 6].

We find the examiner's position untenable.

It is well established that anticipation requires that each and every limitation set forth in a claim be present, either expressly or inherently, in a single prior art reference. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950 (Fed. Cir. 1999); Celeritas Techs. Ltd v. Rockwell Int'l Corp., 150 F.3d 1354, 1360, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984).

Here, we find that the examiner has been a bit creative in order to make his finding that L'Esperance anticipates the claimed invention. That is, the examiner first points to Figure 1 as depicting a plug with an outer surface, and to element 17, in particular, as meeting the limitation of an "outwardly exposed surface." We find that

L'Esperance (col. 3, lines 9-16) describes element 17 as a "flange"; however, we point out that it does not constitute an "outwardly exposed surface" as required by the claims. To the contrary, element 17 is located in the interior portion of the eye as it exposed to the anterior chamber. See Figure 1 and col. 2, lines 55-60. Be that as it may, the creative portion of the examiner's rejection is the combination of the device set forth in Figure 1 with the devices in the figures which L'Esperance describes as containing energy-absorbing compounds; viz., Figures 9-16. The devices in the latter figures differ structurally from the device shown in Figure 1. That is, rather than having an outwardly exposed surface (element 18 in Figure 1) which holds them in position, the latter devices comprise elements 41-42 and 51-52, which are present in a ring surrounding a tube (element 31). Said elements comprise chromophores which are responsive to irradiating wavelengths. L'Esperance, e.g., col. 5, lines 5-49 and col. 6, line 65-col. 7, line 32. We do not find that the structures which comprise the energy-absorbing compounds (dyes or chromophores) resemble the structure set forth in Figure 1 of the patent. Thus, we do not find that L'Esperance discloses the addition of a substance to the device shown in Figure 1 which would make it easily visualized. Nor do we find, and the examiner has not pointed out, a disclosure in L'Esperance that the "energy absorbing compounds" (elements 41-42 and 51-52) cause an outwardly exposed surface of the devices set forth in Figures 9-15 to contrast with the surrounding tissue and enable the plug to be more easily visualized. Rather, we find that L'Esperance only discloses that said compounds will shrink when exposed to different

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irradiating wavelengths. Thus, we do not find that L'Esperance discloses, expressly or inherently, each and every element recited in claims 1-4 and 6.

Accordingly, Rejection 1 is reversed.

## II. Obviousness

The examiner argues that Seder and Freeman each disclose flexible, punctum plugs having an outwardly exposed surface. Answer, p. 4. The examiner acknowledges that the plugs disclosed by Seder and Freeman do not contain a substance which causes them to be more easily visualized (id., p. 5); however, he contends that the teachings of Gwon make up for this deficiency. To that end, the examiner argues that Gwon “explicitly teaches that a tracer may be incorporated into the insert [ophthalmic device] by physical admixture or dissolution into the implant matrix . . . [and the] . . . tracer is able to illuminate with light at its own illumination wavelength.” Id. The examiner contends that “using a tracer in the matrix of an ophthalmic device is a general knowledge available in the art.” Id. Thus, the examiner concludes that

it would have been obvious to one of ordinary skill in the art at the time of invention to employ a tracer such as florescence [sic, fluorescence?] into the matrix of Seder's or Freeman's plugs, because as taught by Gwon, the ordinary artisan would have had a reasonable expectation of success in improving the visualization of the plug in the recipient's eyes [Answer, p. 5].

It is well established that the examiner has the initial burden under § 103 to establish a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445,

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24 USPQ2d 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). To that end, it is the examiner's responsibility to show that some objective teaching or suggestion in the applied prior art, or knowledge generally available [in the art] would have led one of ordinary skill in the art to combine the references to arrive at the claimed invention. Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

Here, we agree with the appellant that Gwon is primarily directed to "a method for determining an amount of medication in an implantable device." Brief, p. 4. Attention is directed, for example, to the abstract which states that "a tracer may be incorporated into the device to enable visual indication of the amount of active agent in said device when said device is disposed under the conjunctiva." We recognize that a reference is not limited to its preferred embodiments or examples, but in considering Gwon in its entirety, we find that the device disclosed therein is not a plug as required by the claims before us, but rather it is an ocular implant made of specific polymers which permit the passage of an active agent or drug through said polymers by diffusion. Gwon, col. 3, lines 26-48. Given the structural differences between the ophthalmic device disclosed by Gwon and the plugs set forth in the claims, we do not find that Gwon's disclosure that the "tracers may be incorporated into the insert by physical admixture or dissolution into the implant matrix" [col. 5, lines 48-50], would have reasonably suggested the incorporation of a substance which is more easily visualized

into a punctum plug. Rather, the only suggestion we find for such a combination is in the appellant's specification. Thus, we find that the examiner has engaged in impermissible hindsight to arrive at the conclusion that the claimed invention would have been obvious over Seder or Freeman, in view of Gwon. In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985); W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 311-313 (Fed. Cir. 1983), cert denied, 469 U.S. 851 (1984) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher").

#### Other Issues


We note that Freeman discloses that "it is believed that silicon, stainless steel, aluminum and other metal and plastic materials which possess the necessary characteristics . . . would prove suitable as the punctum plug materials." Freeman, col. 4, lines 47-55. Upon return of the application to the corps, the examiner may wish to consider whether these teachings would have suggested punctum plugs which are more easily visualized as recited in the claims.




We note that the appellant argues claims 5-7 and 8 separately. See, the Brief, pp. 4-6. However, given our disposition of the case with respect to claim 1, we need not address these issues.

In view of the foregoing, Rejection II is reversed.

REVERSED

  
JOAN ELLIS  
Administrative Patent Judge

  
DONALD E. ADAMS  
Administrative Patent Judge

  
ERIC GRIMES  
Administrative Patent Judge

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